

## PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application : Timothy E. McAlindon, et al.  
 Application No. : 09/560,597  
 Filed : April 28, 2000  
 For : METHOD FOR CONDUCTING CLINICAL TRIALS  
       OVER THE INTERNET  
 Examiner : Kapadia, Milan S.  
 Attorney's Docket : BU-022XX

Group Art Unit: 3626

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 I hereby certify that this correspondence is being sent via facsimile  
 to Examiner Milan S. Kapadia, Group Art Unit 3626, After Final, Fax  
 No. (703) 305-7687, on July 25, 2003.

By

David A. Dagg  
 David A. Dagg  
 Registration No. 376809  
 Attorney for Applicants

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DECLARATION UNDER 37 C.F.R. § 1.131

Via Facsimile  
 Mail Stop AF  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

We, Timothy E. McAlindon and Karim A.N. Kabbara, hereby  
 declare that:

1. We are co-inventors of the claimed subject matter of the  
 above-identified United States patent application.

2. The subject matter of at least claims 1-38 in the above-  
 identified patent application was conceived prior to October,  
 1998, as evidenced by the Clinical Science Grant Application for

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the Research Project entitled "A Study Of The Feasibility Of Internet-Based Clinical Trials In Osteoarthritis" (the "Grant Application", hereafter), signed and dated August 31, 1998, and attached hereto as Exhibit A.

The contents of the Grant Application demonstrate that the requisite components of the present claims and their interaction were well comprehended, and that this comprehension was in our possession, at least as early as August 31, 1998. For example, at page 11 in the Specific Aims section of the Grant Application, the extensive use of a specially designed Web site to provide an Internet-based clinical trial is described, including solicitation of participants, as well as participant screening using validated questions, advertising of the study using Internet based techniques, disease status validation using a validation algorithm, and validated reporting of pain assessment, daily pill use and pill counts, and adverse events. At page 13 of the Grant Application, beginning in paragraph 3, there is further described specifically the desire for data privacy on the behalf of patients. Paragraph 4 on page 13 specifically foresees the danger of potential interception of data posted electronically, and describes the use of encrypted data and sending of data in association with allocated identification numbers to protect the privacy of the user.

The use of a system that employs "unique login names,

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passwords, and by the unique IP address of the user's computer" to maintain participant privacy is clearly stated in paragraph 4 of page 13. The use of such data security measures in the specially designed Web site is further described beginning in the section entitled "Architecture Of The Study Web Site" on page 19 of the Grant Proposal. For example, paragraph 2 of page 19 in the Grant Proposal describes participants using login names and passwords to access evaluative pages. The following sections entitled "Authenticating The Identity of Respondents", "Obtaining Informed Consent", and "Confidentiality And Security Of Information Provided By Participants Over The Internet" also describe the techniques set forth in the present claims. Thus the presently claimed invention was comprehended and in our possession at least as early as when the Grant Proposal was signed on August 31, 1998.

3. Subsequent to the conception of the invention, the inventors exercised diligence through reduction to practice of the invention which occurred at least as early as the constructive reduction to practice of April 29, 1999 upon the filing of the provisional patent application number 60/131,528, from which the present application claims priority. Throughout this time period, program code for an embodiment of the invention was being prepared at least by the undersigned Karim A. N. Kabbara. Mr. Kabbara was originally hired as an outside consultant, and then subsequently

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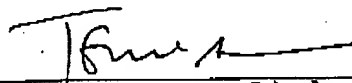
hired as an employee by Boston University for the purpose of developing such program code during this time period. Copies of invoices for services rendered in this regard by Mr. Kabbara, and dated December 7, 1998, January 5, 1999, January 12, 1999, and March 9, 1999, are attached hereto as Exhibits B-E as evidence of these programming activities. Attached hereto as Exhibit F is an example of a Web page screen from Web page code developed by Mr. Kabbara during the time period. Exhibits G and H show example versions of a Web page form developed during the time period, and dated August 14, 1998 and October 19, 1998 respectively. Exhibit I is a file used to build tables and triggers for a prototype database developed during the time period. Exhibit J is a document developed reflecting review of code under development and work to be done in that regard during the critical time period, and Exhibit K shows another Web page form prototype developed during that time period. Exhibit L is a prototype consent form also developed during the critical time period. Exhibit M is a directory printout indicating the last times that the files included herewith as Exhibits B-L were modified, and with references to other files redacted out. As shown in Exhibit M, the file Invoice 2.doc, included herewith as Exhibit B, was last modified on December 7, 1998. The file Invoice 3.doc, included herewith as Exhibit C, was last modified on January 5, 1999. The file Invoice 4.doc, included herewith as Exhibit D, was last

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modified on January 13, 1999. The file Invoice 5.doc, included herewith as Exhibit E, was last modified on March 31, 1999. The file vel.htm, included herewith as Exhibit F, was last modified on November 19, 1998. While the file included herewith as Exhibit G is not listed in the directory of Exhibit M because it predates the directory of Exhibit M, the file bumcac12\_bumc\_bu\_edu.html, included herewith as Exhibit H, which is the subsequent development of that file, was last modified on October 19, 1998. The file bu\_trig.sql, included herewith as Exhibit I, was last modified January 11, 1999, and the file Clinical trials work.doc, included herewith as Exhibit J, was last modified on February 22, 1999. Also as shown in Exhibit M, the file confirmation.htm, included herewith as Exhibit K, was last modified on November 19, 1998, and the file consent.doc, included herewith as Exhibit L, was last modified on October 29, 1998.

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4. Having been duly warned that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the U.S. Code and may jeopardize the validity of the application or any patent issuing thereon, we hereby declare that all statements made of our own knowledge are true and that all statements made on information and belief are believed to be true.

  
Timothy E. McAlindon

7/23/2003  
Dated

  
Karim A.N. Kabbara

7/23/2003  
Dated

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